DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-12RP]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Assessment of the Psychosocial Impact of Newborn Screening for Congenital Cytomegalovirus (CMV) Infection - New – National Center for Immunization and Respiratory Diseases (NCIRD) and National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year in the United States, more than 30,000 children are born with congenital CMV infection. Approximately 80% develop normally, while the remaining 20% are born with or subsequently develop disabilities such as hearing loss or mental retardation. A similar number of children are affected by serious CMV-related disabilities than by several better-known childhood conditions, including Down Syndrome and Spina Bifida.

The birth prevalence of congenital CMV infection is several times higher than the combined birth prevalence of all metabolic or endocrine disorders in the core U.S. newborn screening panel. Because newborn CMV screening is rarely performed, and because a definitive diagnosis of congenital CMV requires access to urine, saliva, or blood collected soon after birth, most infected children are never diagnosed. Newborn CMV screening offers some clear potential benefits, but few studies have assessed the potential for harm (e.g., increased parental anxiety, "fragile child syndrome").

CDC is requesting OMB approval for one year to collect information about newborn CMV screening. The purpose of this information collection is to understand the psychosocial impact of newborn screening on parents whose infants underwent CMV screening as part of a routine infant CMV screening program in

Houston, Texas. The potential study population includes approximately 70 CMV-infected children who were symptomatic at birth, 100 CMV-infected children who were asymptomatic at birth (20 of whom developed sequelae), and 50 controls that were CMV-uninfected. The goals of this information collection are to: 1) document the positive and negative psychosocial impacts of newborn CMV screening on parents and their children; 2) identify modifiable factors that might increase positive psychosocial impacts and decrease negative psychosocial impacts of newborn CMV screening; 3) use what is learned about psychosocial impacts to identify key messages that parents need relative to newborn CMV screening and follow-up; and 4) to learn what challenges are associated with obtaining a congenital CMV diagnosis in the absence of CMV newborn screening.

Much of the potential study population is unique in that their children experienced newborn CMV screening as part of a previous research study. Universal CMV screening has not been recommended by medical associations or state or federal governments and as a result newborn CMV screening is not typically performed. The parents' experience with CMV screening and follow-up will help inform decisions about whether newborn CMV screening would be good public health policy. This study represents the first

assessment of the experiences of parents whose children were screened for CMV at birth.

Respondents fall into four categories depending on the past experiences of their child who was screened for CMV:

- Parent Group 1 (PG1) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did not develop sequelae
- Parent Group 2 (PG2) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did subsequently develop sequelae (e.g., hearing loss)
- Parent Group 3 (PG3) – Child was diagnosed with congenital CMV and had symptoms at birth
- Parent Group 4 (PG4) – Child screened negative for congenital CMV at birth

Information will be collected from PG1 via focus groups, from PG2 and PG3 via interviews, and from all four parent groups via a mail survey. The focus group, interview and survey respondents will be asked to participate only once. It is estimated that 71 parents will participate in either individual interviews or focus groups and that 230 will participate in the mail survey. The interviews are planned to take 60 minutes while the focus groups will be held for 90 minutes. The survey is estimated to

take 10 minutes per respondent to complete and mail based on previous administrations reported in the literature. Reading and responding to the focus group and interview recruitment letters is estimated to take 5 minutes each. There is no cost to respondents other than their time. The annualized estimated burden hours are 135.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)
Parent Group 1	Focus Group Guide	36	1	1.5
	Focus group recruitment letter	50	1	5/60
Parent Groups 2 and 3	Interviewer guide	35	1	1
	Interview recruitment letter	50	1	5/60
Parent Groups 1,2,3, and 4	Survey	230	1	10/60

Dated: January 14, 2013.

_____

Ron A. Otten,
Director, Office of Scientific Integrity (OSI)
Office of the Associate Director for Science (OADS)
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2013-01163 Filed 01/18/2013 at 8:45 am; Publication Date: 01/22/2013]